

PRESCRIPTION DRUG SUNSHINE, TRANSPARENCY,  
ACCOUNTABILITY AND REPORTING ACT

DECEMBER 24, 2020.—Committed to the Committee of the Whole House on the State  
of the Union and ordered to be printed

Mr. NEAL, from the Committee on Ways and Means,  
submitted the following

R E P O R T

[To accompany H.R. 2113]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 2113) to amend titles XI and XVIII of the Social Security Act to provide for drug manufacturer price transparency, to require certain manufacturers to report on product samples provided to certain health care providers, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Prescription Drug Sunshine, Transparency, Accountability and Reporting Act” or the “Prescription Drug STAR Act”.

**SEC. 2. DRUG MANUFACTURER PRICE TRANSPARENCY.**

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128K the following new section:

**“SEC. 1128L. DRUG MANUFACTURER PRICE TRANSPARENCY.**

“(a) IN GENERAL.—With respect to each year, beginning with 2021, the Secretary shall, at least once during such year, determine if there is a triggered SPIKE increase (in accordance with subsection (b)) with respect to an applicable drug (as defined in subsection (f)(1)). If the Secretary determines, with respect to a year, there is such an increase with respect to an applicable drug, the manufacturer of the applicable drug shall submit to the Secretary the justification described in subsection (c), subject to subsection (b)(4), for each such triggered SPIKE increase in accordance with the timing described in subsection (d)).

“(b) TRIGGERED SPIKE INCREASE.—

“(1) IN GENERAL.—A triggered SPIKE increase occurs, with respect to an applicable drug and year (beginning with 2021 and referred to in this paragraph as the ‘applicable year’), in any of the following cases:

“(A) If there is at least a 10 percent (or \$10,000) cumulative increase with respect to the wholesale acquisition cost (or alternative cost measure specified by the Secretary under paragraph (3)) of such drug during a calendar-year period beginning and ending within the lookback period that is the 5-year period preceding such applicable year.

“(B) If there is at least a 25 percent (or \$25,000) cumulative increase with respect to the wholesale acquisition cost (or such alternative cost measure) of such drug during any three-calendar-year period beginning and ending within such lookback period.

“(C) In the case of such a drug that is first covered under title XVIII with respect to such applicable year, if the estimated cost or spending under such title per individual or per user of such drug (as estimated by the Secretary) for such applicable year (or per course of treatment in such applicable year, as defined by the Secretary) is at least \$26,000.

“(2) INDEXING DOLLAR AMOUNTS.—The dollar amounts applied under paragraph (1) for 2022 and each subsequent year shall be the dollar amounts specified in such paragraph for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year. If any amount established under paragraph (1), after application of this paragraph, for a year is not a multiple of \$10, it shall be rounded to the nearest multiple of \$10.

“(3) ALTERNATIVE TO WAC.—The Secretary may, for purposes of making determinations under paragraph (1), in addition to using the wholesale acquisition cost for an applicable drug, use alternative cost measures of such drug, or use such alternative cost measure if the wholesale acquisition cost is not available.

“(4) EXCEPTION.—A justification under subsection (c) shall not be required for a triggered SPIKE increase described in paragraph (1) of an applicable drug of a manufacturer if—

“(A) there is any portion of the lookback period described in the respective subparagraph of such paragraph for such increase that is included within the lookback period for another triggered SPIKE increase (or combination of such increases) for which a justification is made under this section for such drug by such manufacturer; or

“(B) such increase is less than the wholesale acquisition cost (or alternative cost measure specified by the Secretary under paragraph (3)) of such drug during the calendar-year period described in paragraph (1)(A) or the three-calendar-year period described in paragraph (1)(B), as applicable, for such increase, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending six months prior to the calendar-year period so described and for the 36-month period ending six months prior to the three-calendar-year period so described, respectively.

“(5) UNIT DETERMINATION.—For purposes of determining the wholesale acquisition cost in carrying out this section, the Secretary shall determine a unit (such as a unit size) to apply.

“(6) PUBLIC POSTING.—Beginning with respect to 2021, the Secretary shall publicly post on the Internet website of the Department of Health and Human Services—

“(A) alternative percentages, dollar amounts, and lookback periods that, if applied under paragraph (1), would be projected to increase the number of applicable drugs for which a triggered SPIKE increase would occur for such year; and

“(B) the number of applicable drugs for which a triggered SPIKE increase would occur for such year if such an alternative percentage, dollar amount, or period were applied for such year.

“(c) JUSTIFICATION DESCRIBED.—

“(1) IN GENERAL.—The justification described in this subsection, with respect to a triggered SPIKE increase described in subsection (b)(1) of an applicable drug of a manufacturer, is—

“(A) all of the information described in paragraph (2);

“(B) all of the information and supporting documentation described in paragraph (3), as applicable to the increase and drug; and

“(C) a certification described in paragraph (4).

“(2) REQUIRED INFORMATION.—For purposes of paragraph (1), the information described in this paragraph is the following:

“(A) The individual factors that have contributed to the increase in the wholesale acquisition cost.

“(B) An explanation of the role of each factor in contributing to such increase.

“(3) INFORMATION AS APPLICABLE.—For purposes of paragraph (1), the information and supporting documentation described in this paragraph is the following, as applicable to the increase of the drug:

“(A) Total expenditures of the manufacturer on—

“(i) materials and manufacturing for such drug;

“(ii) acquiring patents and licensing for each drug of the manufacturer; and

“(iii) costs to purchase or acquire the drug from another company, if applicable.

“(B) The percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds.

“(C) The total expenditures of the manufacturer on research and development for such drug.

“(D) The total revenue and net profit generated from the applicable drug for each calendar year since drug approval.

“(E) The total costs associated with marketing and advertising for the applicable drug.

“(F) Additional information specific to the manufacturer of the applicable drug, such as—

“(i) the total revenue and net profit of the manufacturer for the period of such increase, as determined by the Secretary;

“(ii) metrics used to determine executive compensation;

“(iii) total expenditures on—

“(I) drug research and development; or

“(II) clinical trials on drugs that failed to receive approval by the Food and Drug Administration; and

“(iv) any additional information related to drug pricing decisions of the manufacturer.

“(G) Any other relevant information and supporting documentation necessary to justify the triggering SPIKE increase.

“(H) Any other relevant information and supporting documentation, as specified by the Secretary.

“(4) CERTIFICATION.—For purposes of paragraph (1), the certification described in this paragraph is a certification, that all such information and documentation is accurate and complete, by one of the following:

“(A) The chief executive officer of the manufacturer.

“(B) The chief financial officer of the manufacturer.

“(C) An individual who has delegated authority to sign for, and who reports directly to, such chief executive officer or chief financial officer.

“(d) TIMING.—

“(1) NOTIFICATION.—Not later than 60 days after the date on which the Secretary makes the determination that there is a triggering SPIKE increase with respect to an applicable drug, the Secretary shall notify the manufacturer of the applicable drug of such determination.

“(2) SUBMISSION OF JUSTIFICATION.—Not later than 90 days after the date on which a manufacturer receives a notification under paragraph (1), subject to subsection (b)(4), the manufacturer shall submit to the Secretary the justification required under subsection (a), including a summary of such justification, in a form and manner specified by the Secretary. In specifying such form, with respect to the summary required under the previous sentence, the Secretary shall provide that such summary shall be in an easily understandable format, as specified by the Secretary, and shall permit the manufacturer to exclude proprietary information from such summary.

“(3) POSTING ON INTERNET WEBSITE.—Not later than 30 days after receiving the complete justification under paragraph (2), the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the summary included for such justification.

“(e) PENALTIES.—

“(1) FAILURE TO SUBMIT TIMELY JUSTIFICATION.—If the Secretary determines that a manufacturer has failed to submit a justification as required under this section, including in accordance with the timing and form required, with respect to an applicable drug, the Secretary shall apply a civil monetary penalty in an amount of \$10,000 for each day the manufacturer has failed to submit such justification as so required.

“(2) FALSE INFORMATION.—Any manufacturer that submits a justification under this section that knowingly provides false information in such justification is subject to a civil monetary penalty in an amount not to exceed \$100,000 for each item of false information.

“(3) APPLICATION OF PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). Civil monetary penalties imposed under this subsection are in addition to other penalties as may be prescribed by law.

“(f) DEFINITIONS.—In this section:

“(1) APPLICABLE DRUG.—

“(A) IN GENERAL.—Subject to subparagraph (B), the term ‘applicable drug’ means, with respect to a lookback period described in subsection (b)(1), a covered outpatient drug (as defined in paragraph (2) of section 1927(k), without application of paragraph (3) of such section) that is covered under title XVIII and is not a low cost drug.

“(B) EXCLUSION OF LOW COST DRUGS.—For purposes of subparagraph (A), not later than January 1, 2021, the Secretary shall specify a threshold (such as a cost or spending threshold) for identifying (and shall identify) low cost drugs to be excluded from the definition of the term ‘applicable drug’, such as a drug that has a wholesale acquisition cost of less than \$10 per unit or less than \$100 in average estimated expenditures under title XVIII per individual per year or per user of such drug per year. For purposes of this section, a drug shall not be considered specified as a low cost drug for a lookback period described in subsection (b)(1) with respect to a year unless such drug is identified as being below the specified threshold for the entirety of the lookback period.

“(2) MANUFACTURER.—The term ‘manufacturer’ has the meaning given that term in section 1847A(c)(6)(A).

“(3) WHOLESALE ACQUISITION COST.—The term ‘wholesale acquisition cost’ has the meaning given that term in section 1847A(c)(6)(B).”.

(b) REPORTING TO THE SECRETARY OF THE TREASURY.—

(1) IN GENERAL.—Subpart A of part III of subchapter A of chapter 61 of the Internal Revenue Code of 1986 is amended by inserting after section 6039J the following new section:

**“SEC. 6039K. DRUG PRICE SPIKE INCREASE REPORTING.**

“Each manufacturer (within the meaning of section 1128L of the Social Security Act) shall file a return (at such time and in such form and manner as the Secretary may provide) showing for such year with respect to which such section applies all information and supporting documentation and the certification included within a justification reported by the manufacturer under subsection (c)(1) of such section.”.

(2) CLERICAL AMENDMENT.—The table of sections for subpart A of part III of subchapter A of chapter 61 of such Code is amended by inserting after the item relating to section 6039J the following new item:

“Sec. 6039K. Drug price SPIKE increase reporting.”.

**SEC. 3. REQUIREMENT FOR MANUFACTURERS OF CERTAIN DRUGS, DEVICES, BIOLOGICALS, AND MEDICAL SUPPLIES TO REPORT ON PRODUCT SAMPLES PROVIDED TO CERTAIN HEALTH CARE PROVIDERS.**

(a) IN GENERAL.—Section 1128G(a) of the Social Security Act (42 U.S.C. 1320a–7h(a)) is amended by adding at the end the following new paragraph:

“(3) CERTAIN PRODUCT SAMPLES.—

“(A) IN GENERAL.—In addition to the requirements under paragraphs (1)(A) and (2), on the 90th day of each calendar year (beginning with 2023), any applicable manufacturer that provides a payment or other transfer of value that is a product sample described in subparagraph (B) to any covered recipient (or to an entity or individual at the request of, or designated on behalf of, such a covered recipient) shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information (aggregated per each drug, device, biological, or medical supply, as applicable) with respect to the preceding calendar year:

“(i) The total quantity of all such payments or other transfers of value provided to all covered recipients.

“(ii) The total value of all such payments or other transfers of value provided to all covered recipients.

“(iii) If applicable, information described in clauses (vii) and (viii) of paragraph (1)(A) with respect to such a payment or other transfer of value.

“(B) PRODUCT SAMPLE DESCRIBED.—For purposes of subparagraph (A), a product sample described in this subparagraph is a product sample that is not intended to be sold and is intended for patient use.”.

(b) PUBLIC AVAILABILITY OF INFORMATION.—Section 1128G(c)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1320a–7h(c)(1)(C)(ii)) is amended—

(1) by striking “(ii) contains” and inserting “(ii)(I) with respect to information that is not information submitted under paragraph (3) of subsection (a), contains”;

(2) by striking “, as applicable;” and inserting “, as applicable; and”; and

(3) by adding at the end the following new subclause:

“(II) with respect to information submitted under paragraph (3) of subsection (a), contains information that is presented by the name of the applicable manufacturer, the total amount of all payments or other transfers of value described in such paragraph provided to all covered recipients, the total value of all such payments or other transfers of value provided to all covered recipients, and the name of the covered drug, device, biological, or medical supply, as applicable;”.

(c) CONFORMING AMENDMENT.—Section 1128G(e)(10)(B)(ii) of the Social Security Act (42 U.S.C. 1320a–7h(e)(10)(B)(ii)) is amended by striking “Product samples” and inserting “Except for purposes of paragraph (3) of subsection (a), product samples”.

(d) REPORTING TO THE SECRETARY OF THE TREASURY.—

(1) IN GENERAL.—Subpart A of part III of subchapter A of chapter 61 of the Internal Revenue Code of 1986, as amended by section 2, is further amended by inserting after section 6039K the following new section:

**“SEC. 6039L. PRODUCT SAMPLES OF APPLICABLE MANUFACTURERS.**

“Each applicable manufacturer (within the meaning of section 1128G(a)(3) of the Social Security Act) shall file a return (at such time and in such form and manner as the Secretary may provide) showing for such year to which such section applies—

“(1) the amount described in section 1128G(a)(3)(A)(ii) of such Act with respect to such year, and

“(2) the portion of such amount for which a deduction was claimed under section 162.”.

(2) CLERICAL AMENDMENT.—The table of sections for subpart A of part III of subchapter A of chapter 61 of such Code, as amended by section 2, is further

amended by inserting after the item relating to section 6039K the following new item:

“Sec. 6039L. Product samples of applicable manufacturers.”.

**SEC. 4. ANALYSIS AND REPORT ON INPATIENT HOSPITAL DRUG COSTS.**

(a) ANALYSIS.—The Secretary of Health and Human Services shall conduct an analysis that, to the extent practicable—

- (1) focuses on drugs that are furnished in the inpatient setting;
- (2) includes data on inpatient hospital drug costs, Medicare spending, volume, and spending per admission;
- (3) considers trends in inpatient hospital drug costs, such as trends by hospital size, classification of urban or rural, whether the hospital is a teaching hospital, or other categorization; and
- (4) examines the impact of drug shortages on services that are furnished in an inpatient hospital setting.

In conducting such analysis, the Secretary may conduct hospital surveys, use data from hospital cost reports, or use other data as determined by the Secretary.

(b) REPORT.—Not later than January 1, 2021, the Secretary shall submit to the Committee on Ways and Means of the House of Representatives and the Finance Committee of the Senate a report on drug costs in the inpatient hospital setting, including the analyses described in paragraphs (1) through (4) of subsection (a).

(c) FUNDING.—For purposes of carrying out this section, there shall be transferred to the Secretary \$3,000,000 from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i).

**SEC. 5. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) in subsection (c), in the matter preceding paragraph (1), by inserting “(other than as permitted under subsection (e))” after “disclosed by the Secretary”; and

(2) by adding at the end the following new subsection:

“(e) PUBLIC AVAILABILITY OF CERTAIN INFORMATION.—

“(1) IN GENERAL.—In order to allow the comparison of PBMs’ ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions that are passed through to plan sponsors, beginning January 1, 2020, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information with respect to the second preceding calendar year provided to the Secretary on generic dispensing rates (as described in paragraph (1) of subsection (b) and information provided to the Secretary under paragraphs (2) and (3) of such subsection that, as determined by the Secretary, is with respect to each PBM.

“(2) AVAILABILITY OF DATA.—In carrying out paragraph (1), the Secretary shall ensure the following:

“(A) CONFIDENTIALITY.—The information described in such paragraph is displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions, with respect to an individual drug or an individual plan.

“(B) CLASS OF DRUG.—The information described in such paragraph is made available by class of drug, using an existing classification system, but only if the class contains such number of drugs, as specified by the Secretary, to ensure confidentiality of proprietary information or other information that is prevented to be disclosed under subparagraph (A).”.

**SEC. 6. REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM.**

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended—

(1) in subsection (b)—

(A) in paragraph (2)(A), by inserting “or subsection (f)(2), as applicable” before the period at the end;

(B) in paragraph (3), in the matter preceding subparagraph (A), by inserting “or subsection (f)(2), as applicable,” before “determined by”; and

(C) in paragraph (6)(A), in the matter preceding clause (i), by inserting “or subsection (f)(2), as applicable,” before “determined by”; and

(2) in subsection (f)—

(A) by striking “For requirements” and inserting the following:

“(1) IN GENERAL.—For requirements”; and

(B) by adding at the end the following new paragraph:

“(2) MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.—

“(A) IN GENERAL.—In the case of a manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in clause (ii) or (iii) of section 1881(b)(14)(B) that does not have a rebate agreement in effect under section 1927, for calendar quarters beginning on or after January 1, 2020, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary.

“(B) AUDIT.—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

“(C) VERIFICATION.—The Secretary may survey wholesalers and manufacturers that directly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer’s average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(D) CONFIDENTIALITY.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

“(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

“(ii) to permit the Comptroller General to review the information provided; and

“(iii) to permit the Director of the Congressional Budget Office to review the information provided.”.

(b) ENFORCEMENT.—Section 1847A such Act (42 U.S.C. 1395w–3a) is further amended—

(1) in subsection (d)(4)—

(A) in subparagraph (A), by striking “IN GENERAL” and inserting “MISREPRESENTATION”;

(B) in subparagraph (B), by striking “subparagraph (B)” and inserting “subparagraph (A), (B), or (C)”;

(C) by redesignating subparagraph (B) as subparagraph (D); and

(D) by inserting after subparagraph (A) the following new subparagraphs:

“(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of \$10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.

“(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.”; and

(2) in subsection (c)(6)(A), by striking the period at the end and inserting “, except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.”.

(c) REPORT.—Not later than January 1, 2021, the Inspector General of the Department of Health and Human Services shall assess and submit to Congress a report on the accuracy of average sales price information submitted by manufacturers under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a). Such report shall include any recommendations on how to improve the accuracy of such information.

## I. SUMMARY AND BACKGROUND

### A. PURPOSE AND SUMMARY

The bill, H.R. 2113, the “Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019” as ordered reported by the Committee on Ways and Means on April 9, 2019, includes several provisions that amend Titles XI and XVIII of the Social Security Act (SSA) and focuses on increasing transparency in the pharmaceutical marketplace. Specifically, H.R. 2113 requires pharmaceutical manufacturers to justify drug price increases or market introduction prices that exceed a threshold amount, including reporting expenditures for research and development and other costs; adds new reporting requirements for medical product samples under the existing federal Open Payments program; and requires the Secretary of the Department of Health and Human Services (HHS) to post on the public HHS website the aggregate rebates and discounts that Pharmacy Benefit Managers (PBMs) receive from drug manufacturers, by class of drug. The bill also requires drug manufacturers that do not currently report Medicare Part B drug prices to report those prices, and it requires the Secretary to collect additional information on prescription drugs used for inpatient hospital care covered under Medicare Part A.

H.R. 2113 incorporates provisions that are substantially similar to a number of bills that have been introduced as standalone measures this Congress. Notably, section 2 is adapted from H.R. 2069, introduced by Representative Horsford (D–NV) and Representative Reed (R–NY). In addition, section 3 is adapted from H.R. 2064, introduced by Representative Chu (D–CA) and Representative Nunes (R–CA); section 5 is adapted from H.R. 2115, introduced by Representative Spanberger (D–VA), Arrington, (R–TX), and Boyle (D–PA); and section 6 is adapted from H.R. 2087, which was introduced by Subcommittee on Health Chairman Doggett (D–TX) and Representative Buchanan (R–FL).

### B. BACKGROUND AND NEED FOR LEGISLATION

The United States spent \$457 billion on prescription drugs in 2016, consisting of \$328 billion on retail drugs and \$128 billion on non-retail drugs. This figure represents approximately 17 percent of all health care spending.<sup>1</sup> Between 2011 and 2016, drug spending nationwide grew by 27 percent, more than 2.5 times the rate of growth in inflation.<sup>2</sup> Medicare alone spent nearly \$130 billion on prescription drugs in 2016, \$99.5 billion of which was for Part D drugs (drugs at the pharmacy counter) and \$29.1 billion of which was for Part B drugs (drugs in a physician’s office).<sup>3</sup> In total, 20

<sup>1</sup> Assistant Secretary for Planning and Evaluation: Department of Health and Human Services. *Observations on Trends in Prescription Drug Spending*. MARCH 8, 2016. <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>.

<sup>2</sup> Office of the Actuary: Center for Medicare and Medicaid Services (CMS). *2016 National Health Expenditures: National Health Prescription Drug Spending Data, Table 11, BLS data on CPI-U 2011–2016*. December 6, 2017. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

<sup>3</sup> Kaiser Family Foundation, *10 Essential Facts About Medicare and Prescription Drug Spending*. Jan 2019.



percent of Medicare spending went to prescription drug costs in 2016.<sup>4</sup>

Pharmaceutical spending has risen at an accelerated pace in recent years due to increased utilization, price increases for existing drugs, high launch prices of new products, and a diminishing impact from the introduction of lower cost generic drugs to the market. According to National Health Expenditure data, spending for outpatient drugs rose 29 percent from 2011 to 2017.<sup>5</sup>

Manufacturers set list prices for drugs, which are subject to markups and discounts by wholesalers, pharmacies, and other entities along the drug distribution chain. Manufacturers also negotiate price concessions with PBMs that contract with, or are owned by, health plans that pay for health services.<sup>6</sup> Manufacturers may provide rebates or other price concessions to PBMs to have their drugs listed on health plan formularies (i.e., lists of covered drugs).

Much of the data on pharmaceutical pricing is confidential, through either contract or statutory provision. This makes it difficult for researchers and policymakers to determine the dollar amount of markups and discounts by wholesalers, PBMs, and pharmacies, as well as final or net prices of drugs purchased through payers, including the Medicare program and commercial health plans.<sup>7</sup> For example, HHS collects information about drug prices for the Medicare Part D outpatient prescription drug program, but much of the data may not be released to the public.<sup>8</sup>

In a 2017 report on pharmaceutical pricing, the National Academies of Sciences, Engineering, and Medicine noted that manufacturers, health plans, PBMs and other market participants offered contrasting statements about which players bore responsibility for rising drug prices, often without relevant evidence to support the claims.<sup>9</sup> According to the report, greater disclosure and public reporting of reliable information about prescription drug prices could improve market performance, as has been the case with data reporting requirements for other U.S. industries. Several states have enacted legislation requiring pharmaceutical manufacturers to publicly disclose drug pricing data.<sup>10</sup>

### C. LEGISLATIVE HISTORY

#### *Background*

H.R. 2113 was introduced on April 8, 2019, and was referred to the Committee on Ways and Means and additionally to the Committee on Energy and Commerce.

<sup>4</sup>*Id.*

<sup>5</sup>Office of the Actuary: Center for Medicare and Medicaid Services (CMS). *2016 National Health Expenditures: Historical*. December 6, 2017. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>. The rate of spending increase has slowed to 0.4% in 2017 from a recent peak of 12.4% in 2014.

<sup>6</sup>Ernst Berndt, National Bureau of Economic Research, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*. Working Paper 16297. (September 2010).

<sup>7</sup>*Id.*

<sup>8</sup>42 U.S.C. § 1396r-8(b)(3)(D). (2009).

<sup>9</sup>National Academies of Sciences, Engineering, and Medicine, *Making Medicines affordable: A National Imperative*. The National Academies Press, p. 63. (2017) <https://doi.org/10.17226/24946>.

<sup>10</sup>National Academy for State Health Policy, *State Laws Help Spur Congressional Action on Drug Prices*. (February 19, 2019) <https://nashp.org/state-laws-help-spur-congressional-action-on-drug-prices/>.

### *Committee hearings*

On February 12, 2019, the Committee on Ways and Means held a full committee hearing to examine the cost of rising prescription drug prices. Specifically, the hearing focused on: rapidly escalating prices of older medications, high launch prices, misaligned incentives for responsibly pricing products, and high costs to patients. Members discussed the importance of price transparency, reforms to Medicare Parts B and D, and changes in ASP reporting. Among the Witnesses were Rachel Sachs, Professor of Law at Washington University in St. Louis, who spoke about the misaligned incentives for pharmaceutical payment systems and Alan Reuther, Legislative Consultant at the UAW Retiree Medical Benefits Trust who spoke about increased pharmaceutical costs for their beneficiaries.

On March 7, 2019, the Committee on Ways and Means Subcommittee on Health held a hearing to examine the complicated drug pricing landscape, exploring ways to lower prescription drug prices—particularly as they pertain to patient out-of-pocket costs—through competition and value-based payments. Witnesses, such as Mark Miller, Executive Vice President at Arnold Ventures, discussed the importance of closing tax loopholes in the pharmaceutical market, including the implications of reporting free samples.

### *Committee action*

The Committee on Ways and Means marked up H.R. 2113, the Prescription Drug STAR Act, on April 9, 2019, and ordered the bill, as amended, favorably reported by a voice vote (with a quorum being present).

## **II. EXPLANATION OF THE BILL**

### **A. SECTION 2—DRUG MANUFACTURER PRICE TRANSPARENCY**

#### **CURRENT LAW <sup>11</sup>**

Under current law, the HHS Secretary has the authority to monitor federal health care drug expenditures under Medicare, the Veterans Health Administration, Medicaid, the state Children’s Health Insurance Program, the Public Health Service, and other federal agencies. Generally, federal health program payments for prescription drugs are statutorily determined and often require drug manufacturers to provide price concessions, purchase discounts, or rebates. The HHS Secretary uses a variety of methods to monitor federal drug purchases to ensure compliance with statutory requirements. However, drug manufacturers are not required to explain or justify their pricing strategies and patients are expected to pay the price or risk health complications, bankruptcy, or even death.<sup>12</sup>

<sup>11</sup> All discussions of Current Law in this report refer to current law as of the date of the markup (i.e., April 9, 2019) and do not reflect subsequent law changes.

<sup>12</sup> D. Herkert, P. Vijayakumar, J. Luo, et al., *Cost-Related Insulin Underuse Among Patients with Diabetes*, JAMA Intern Med. 179(1):112–114 (2019); Bram Sable-Smith, *Insulin’s High Cost Leads To Lethal Rationing*, NPR, (2018) <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>; Micaela Marini Higgs, *The High Price of Insulin Is Literally Killing People*, Vice, (2017) [https://tonic.vice.com/en\\_us/article/ezwzwe/the-high-price-of-insulin-is-literally-killing-people](https://tonic.vice.com/en_us/article/ezwzwe/the-high-price-of-insulin-is-literally-killing-people); Amanda Gilbert, *Dubuque County Mom Says Diabetic Son Rationed Insulin, Died*, KWWL, (2018) <https://kwwl.com/news/2018/11/20/dubuque-county-mom-says-diabetic-son-rationed-insulin-died/>.

To comply with federal statute, drug manufacturers and other entities, such as health insurers and PBMs, are required to regularly report certain drug prices and related information to the HHS Secretary. Some statutorily required drug price data may be limited to specific programs or agencies, and most reported pricing information is statutorily protected and confidential as drug manufacturers and other entities consider drug prices to be competitive information. Most drug price data are limited to use by the HHS Secretary for program administration and for review by federal oversight agencies. However, some drug price information is publicly available in aggregate or in other form provided that an individual drug, manufacturer, or payer is not identifiable.

#### REASONS FOR CHANGE

Drafted into Title XI of the SSA alongside a number of other Medicare-related transparency provisions (e.g., Open Payments, PBMs), section 2 of H.R. 2113 requires drug manufacturers to justify to the Secretary of HHS any drug price hikes above 10 percent or \$10,000 per year, or 25 percent or \$25,000 in three years, and for new drugs with a launch price at or above \$26,000 per year. Section 2 of H.R. 2113 provides that the \$10,000, \$25,000, and \$26,000 thresholds will be adjusted by the consumer price index for urban customers (CPI-U) over time.

Drug prices have been increasing astronomically over the past 20 years, and the lack of transparency creates an information asymmetry between the buyer and the seller. For example, the price of Evzio, an opioid overdose medication, increased 508 percent between 2015 and 2016; while the cost of the EpiPen 2-pack increased more than 28 percent for the third year in a row.<sup>13 14 15</sup> In addition, per-capita retail prescription drug spending has almost tripled since 2000.<sup>16</sup> From 2008 to 2016, oral brand name drugs increased 9.2 percent per year, oral specialty drugs increased 20.6 percent per year, and generic drugs have increased at twice the rate of inflation.<sup>17</sup> The Congressional Budget Office (CBO) recently published a report that pointed to launch prices as the culprit in higher prices for specialty drugs in Part D: “The much higher prices of specialty drugs . . . was attributable to the higher prices at which those drugs were introduced, not to more rapid growth in prices following their introduction.”<sup>18</sup>

This provision does not outlaw increases in drug prices or high launch prices—it simply requires an explanation. This provision of the STAR Act requires a public explanation for the rationale be-

<sup>13</sup> Darrell Hulisz et. al, *The Soaring Price of EpiPen*. RN. (2016) <https://www.rn.com/featured-stories/the-soaring-price-of-epipen/>.

<sup>14</sup> C. Koons & R. Langreth, *How Marketing Turned the EpiPen into a Billion-Dollar Business* *Bloomberg.com* (2015) <https://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business>.

<sup>15</sup> Centers for Medicare & Medicaid Services, *Medicare Part D Spending Dashboard and Data*. (2019) <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html>.

<sup>16</sup> Peterson-Kaiser Health System Tracker, *What are the recent and forecasted trends in prescription drug Spending?* (2017) <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-nominal-and-inflation-adjusted-increase-in-rx-spending>. 2017.

<sup>17</sup> Hernandez I, Good CB, Cutler DM, et al. *The Contribution of New Product Entry versus Existing Product Inflation in the Rising Costs of Drugs*. Health Affairs 38. No. 1: 76-83 (2019).

<sup>18</sup> Congressional Budget Office, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis, Working Paper*. (2019) <https://www.cbo.gov/publication/5501>.

hind price increases and high launch prices. The provision includes certain guardrails for drug companies, allowing proprietary information to remain confidential, but it requires drug manufacturers to submit all information as applicable to justifying the price. Due to the heterogeneity of drug pricing across manufacturers and drugs, the bill leaves the required elements used to justify price increases to the discretion of the Secretary, which will be determined through the public comment and rulemaking process. While the elements included in a given submission will ultimately be the responsibility of the manufacturers, the provision requires each manufacturer to attest to the veracity of the justification in writing and manufacturers will be subject to a civil monetary penalty (CMP) for the provision of false information.

When this provision takes effect in 2021, the first reporting period will look back over the preceding five years (increases that occurred from 2016 on) to determine whether a drug qualifies for reporting under the Act. The provision's thresholds and lookback are based on the model law drafted by the National Academy of State Health Policy.<sup>19</sup> Without this lookback period, manufacturers could undermine the goal of transparency by raising their prices as high as possible until 2021 to avoid having to report under the provision. Prices have been continuing to skyrocket and eliminating the lookback on enactment would allow manufacturers to continue their current trend of price increases for their products until 2021 with no justification and no relief in sight for consumers.

This provision also would require reporting for any drug that launches with an annual price of \$26,000 or more. The goal of this provision is to shed light on the factors driving high launch prices and exert pressure on manufacturers to only set high prices when they can be adequately justified. The threshold is set at the median annual income of a Medicare beneficiary. The majority of seniors and Medicare beneficiaries in this country live on fixed income and do not have the flexibility needed to absorb the costs of unexpected medical expenses and increasing drug prices. Half of Medicare beneficiaries have an annual income of less than \$26,200.<sup>20</sup> One quarter of Medicare beneficiaries live on less than \$15,250 per year.<sup>21</sup>

Representative George Holding (R-NC) offered and withdrew an amendment that would have exempted price justifications for drugs launching at or above the \$26,000 threshold if those drugs were the first Food and Drug Administration (FDA)-approved drug for an indication or had fast-track, breakthrough, or orphan drug status. This amendment would have undercut the provision, creating a loophole for drug companies justifying the price of some of the highest cost drugs on the market. Seven of the top ten best-selling drugs in the country in 2015 were orphan drugs, and the median launch price of orphan drugs has doubled every five years since 1983.<sup>22 23</sup>

<sup>19</sup> NASHP, *Drug Price Transparency Model Legislation and Resources*, <https://nashp.org/drug-price-transparency/>.

<sup>20</sup> Gretchen Jacobson et al., *Income and Assets of Medicare Beneficiaries, 2016-2035*. The Henry J. Kaiser Family Foundation. (2017) <https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/>.

<sup>21</sup> *Id.*

<sup>22</sup> Tribble, SJ & Lupkin, S. *Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies*, *Kaiser Health News*. (January 17, 2017) <https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/>.

Many drugs with a high launch price represent a new treatment or cure for previously unmanageable conditions. This law will provide an opportunity for manufacturers to describe their achievements and the incredible value of their innovation, while discouraging needlessly high launch prices for drugs that are not novel cures and may be repackaged as generics.

#### EXPLANATION OF PROVISIONS

This legislation will bring much-needed transparency and accountability in drug prices by requiring that manufacturers justify certain price increases or price launches in excess of the median Medicare beneficiary income.<sup>24</sup> Specifically, section 2 amends the SSA Section 1128 by adding a new section that would require the HHS Secretary to determine at least annually if drug manufacturers have increased currently marketed or newly introduced prescription drug prices by more than certain threshold amounts beginning in 2021. If the HHS Secretary determines a drug's price increased or an introductory price was above the threshold, then drug manufacturers will be required to submit information to justify drug price increase. (Hereinafter the justification required by drug manufacturers that would apply to both drug price increases and introductory prices above a threshold is referred to as the "drug price increase justification.")

Beginning in 2021, the HHS Secretary would be authorized to require drug manufacturers to justify individual drug price increases when a drug's wholesale acquisition cost (WAC), or list price, had:<sup>25</sup>

1. a cumulative WAC (or alternative cost measure specified by the HHS Secretary) increase of at least 10 percent (or \$10,000) within a calendar year period beginning and ending within the five-year lookback period preceding the applicable year;
2. a cumulative WAC (or alternative cost measure) increase of at least 25 percent (or \$25,000) during any three-year period beginning and ending within the lookback period; or
3. an introductory (launch) price of at least \$26,000 per individual or per drug user expenditure (as estimated by the HHS Secretary) for an applicable year or per course of treatment (as defined by the HHS Secretary) for a drug first covered by Medicare.

Beginning with 2022, the drug price thresholds will be adjusted annually for inflation based on the CPI-U as of September of the previous year and rounded to the nearest \$10 multiple. A price increase justification would not be required if: (1) a prior justification occurring within the lookback period had already been triggered, or (2) if the increase were to be less than the inflation adjustment.

Beginning in 2021 and annually thereafter, the HHS Secretary is required to post on a public HHS website information about af-

<sup>23</sup> Johnson, CY. *High Prices Make Once-neglected 'orphan' drugs a booming business*, The Washington Post. (August 4, 2016) [https://www.washingtonpost.com/business/economy/high-prices-make-once-neglected-orphan-drugs-a-booming-business/2016/08/04/539d0968-1e10-11e6-9c81-4be1c14fb8c8\\_story.html?utm\\_term=.a5848b6c94f6](https://www.washingtonpost.com/business/economy/high-prices-make-once-neglected-orphan-drugs-a-booming-business/2016/08/04/539d0968-1e10-11e6-9c81-4be1c14fb8c8_story.html?utm_term=.a5848b6c94f6).

<sup>24</sup> Gretchen Jacobson et al., *Income and Assets of Medicare Beneficiaries, 2016-2035 The Henry J. Kaiser Family Foundation* (2017) <https://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/>.

<sup>25</sup> 1847A(c)(6)(B).

affected drugs if different price increase or introductory price criteria were applied.

Drug manufacturers will be required to justify drug price increases or introductory prices by identifying factors that contributed to the drug's price and the role each factor played in the increase or introductory price. Section 2 requires drug manufacturers to submit the following supporting documentation, as relevant:

- total drug manufacturer expenditures on the following: materials and manufacturing for the drug, patents and licensing acquisition for each drug of the manufacturer, and costs of purchasing or acquiring the drug from another company, if applicable;
- the percentage of the manufacturer's total research and development expenditures for the drug that were derived from federal funds;
- the drug manufacturer's total research and development expenditures for the drug;
- the total revenue and net profit generated by the applicable drug for each calendar year since the drug was approved;
- the drug manufacturer's total marketing and advertising costs for the drug;
- the following additional information specific to the manufacturer such as: the drug manufacturer's total revenue and net profit for the reporting period (as determined by the HHS Secretary), metrics used to determine executive compensation, total expenditures on research and development, total expenditures on clinical trials that failed to gain approval, and any information related to the drug pricing decision;
- any other relevant information and supporting documentation necessary to justify a drug's price increase or introductory price; and
- any other relevant information and supporting documentation as specified by the HHS Secretary.

Drug manufacturers are required to submit a certification signed by the manufacturer's officers (or designees) that the justification information provided was complete and accurate.

The HHS Secretary is required to notify a drug manufacturer within 60 days from the date the HHS Secretary determined that a drug's price increase or introductory price would require justification. Drug manufacturers are required to submit the drug price increase justification, including a summary, within 90 days after being notified by the HHS Secretary. In specifying the justification, the HHS Secretary will be required to permit drug manufacturers to exclude proprietary information from the summary. The HHS Secretary is required to publicly post the summary of the drug price increase justification on the Centers for Medicare & Medicaid Services (CMS) website within 30 days after receiving the drug manufacturer's complete drug price increase justification.

The HHS Secretary is required to apply a \$10,000 per day CMP for each day a drug manufacturer failed to submit a timely drug price increase justification, including failure to submit the justification in the required form and manner. Drug manufacturers that knowingly submitted false price increase justification information would be subject to CMPs up to \$100,000 for each false information

item. Other federal health care CMPs would also apply to reporting of the drug price increase justification.<sup>26</sup>

Section 2 defines applicable drugs as prescription drugs (and biologic products), including insulin, but not vaccines, drugs covered by Medicare during a lookback period that were not low-cost drugs, were approved by the FDA, and were inpatient drugs, physician-administered drugs, or drugs that could be paid for as part of another service.<sup>27</sup> By January 1, 2021, the HHS Secretary would be required to specify a threshold, such as a cost or spending threshold, and to

identify low-cost drugs to exclude from the definition of an applicable drug. Drug manufacturers and WAC are defined consistent with Medicare and Medicaid statute.<sup>28</sup>

Section 2 also requires the Secretary of Treasury to establish a tax return for drug manufacturers if they were required to submit a drug price increase justification. The return would include all the information, supporting documentation, and the certification required in the price justification.

#### EFFECTIVE DATE

The effective date of Section 2 is January 1, 2021.

#### B. SECTION 3—REQUIREMENT FOR MANUFACTURERS OF CERTAIN DRUGS, DEVICES, BIOLOGICALS, AND MEDICAL SUPPLIES TO REPORT ON PRODUCT SAMPLES PROVIDED TO CERTAIN HEALTH CARE PROVIDERS

##### CURRENT LAW

To promote transparency and prevent inappropriate relationships, Section 1128G of the Social Security Act (SSA) generally requires “manufacturers of a covered drug, device, biological, or medical supply”<sup>29</sup> (manufacturers) to report payments or transfers of value to “covered recipients” annually to the HHS Secretary.<sup>30</sup> Under Section 1128G, covered recipients include teaching hospitals and physicians but exclude manufacturers’ employees.<sup>31</sup> Examples of reportable payments and transfers of value include research support, gifts, entertainment, consulting fees, grants, meals, or travel,<sup>32</sup> but exclude certain small payments or transfers of value and product samples that are not intended to be sold and are for patient use.<sup>33</sup> Additionally, Section 1128G directs the HHS Secretary to make submitted information publicly available, including

<sup>26</sup> 42 U.S.C. § 1320(a)–7(a).

<sup>27</sup> Covered outpatient drugs, as defined under Medicaid.

<sup>28</sup> Wholesale Acquisition Cost: 42 U.S.C. § 1395w–3a; Manufacturer: 42 U.S.C. § 1396r–8.

<sup>29</sup> A “covered drug, device, biological, or medical supply” is generally defined as “any drug, biological product, device, or medical supply for which payment is available under Medicare, Medicaid, or CHIP (or a waiver of such a plan). See 42 U.S.C. § 1320a–7h(e)(5).

<sup>30</sup> See *id.* 42 U.S.C. § 1320a–7h(a).

<sup>31</sup> See *id.* § 1320a–7h(e)(6). Section 6111 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) amends Section 1128G(e)(6) to expand the definition of covered recipient to encompass physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. Pub. L. No. 115–271, § 6011(a). The amendments made by this section apply to information required to be submitted on or after January 1, 2022.

<sup>32</sup> 42 U.S.C. § 1320a–7h(a)(1)(A)(vi).

<sup>33</sup> *Id.* § 1320a–7h(e)(10)(B).

through a searchable Internet website,<sup>34</sup> a requirement currently met through the Open Payments program.<sup>35</sup>

In addition, Section 162 of the Internal Revenue Code permits a deduction for ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade or business.<sup>36</sup> Under this section, the cost of producing pharmaceutical product samples may be claimed by a manufacturer as an ordinary and necessary business expense deduction to lower the manufacturer's federal income tax liability for the year in which the samples are distributed to providers.<sup>37</sup>

#### REASONS FOR CHANGE

In 2016, pharmaceutical companies gave the equivalent of \$13.5 billion in free samples to medical care providers.<sup>38</sup> However, little is known about the quantities of products these companies provide. While free drug samples can be incredibly important to patients both for the purposes of trying a new drug to determine its effectiveness or for helping patients afford high-cost drugs, they can also serve as a marketing tool and may have the potential to affect the behavior of patients and providers.<sup>39</sup>

Accordingly, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress collect data and allow public availability of data on free samples. In its report to Congress, MedPac, stated:

*“While free samples may benefit the patient, there are concerns they may influence physicians’ prescribing decisions and lead physicians and patients to rely on more expensive drugs when less expensive medications might be equally effective. More information about the distribution of samples would enable researchers to study their impact on prescribing patterns and overall drug costs and could help payers and health plans target their counter detailing programs. Therefore, the Commission recommends that the Congress require pharmaceutical manufacturers to report information about samples and their recipients.”*<sup>40</sup>

Beyond drugs, transparency is needed for free medical devices. Free samples for devices are no different than free samples of prescription drugs: they are a marketing tool to develop brand loyalty. Little is known, however about the value of many of these products or how many of these products are given out for “free” as a marketing tool to help build brand loyalty. Free products can drive con-

<sup>34</sup> See *id.* § 1320a-7h(c).

<sup>35</sup> Centers for Medicare and Medicaid Services, *Open Payments*. (2019) <https://www.cms.gov/OpenPayments/index.html/>.

<sup>36</sup> 26 U.S.C. § 162(a).

<sup>37</sup> Department of the Treasury, *I.R.S. Nat’l Office Field Serv. Adv. Mem. 199925009*. (June 25, 1999) <https://www.irs.gov/pub/irs-wd/9925009.pdf>.

<sup>38</sup> Schwartz, L. & Woloshin, S. *Medical Marketing in the United States, 1997-2016*. JAMA. (January 2019) [https://jamanetwork.com/journals/jama/fullarticle/2720029?alert=article&utm\\_source=newsletter&utm\\_medium=email&utm\\_campaign=newsletter\\_axiosvitals&stream=top](https://jamanetwork.com/journals/jama/fullarticle/2720029?alert=article&utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top).

<sup>39</sup> Chew LD, O’Young TS, Hazlet TK, Bradley KA, Maynard C, Lessler DS. *A Physician Survey of The Effect of Drug Sample Availability on Physicians’ Behavior*. J Gen Intern Med. 15:478–483. (2000). See e.g., Lahey, T, *The High Costs of “Free” Drug Samples*. (December 2014) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4274368/>. See e.g., Chimonas, S & Kassirer, J, *No more free drug samples?* PloS Med. (2009). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2669216/>.

<sup>40</sup> Medicare Payment Advisory Committee, *Report to Congress: Medicare Payment Policy*. (March 2009) <http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf>.



keting tool to help build brand loyalty. Free products can drive consumers to more expensive devices, which then increase health costs overall. Current physician sunshine reporting shows that device manufacturers provide more “transfers of value” to physicians and teaching hospitals than drug manufacturers: Device donations accounted for \$1.7 billion of the \$2.8 billion in non-research payments to physicians in 2015, or 59 percent of the total. However, that information has yet to be publicly reported.<sup>41</sup>

#### EXPLANATION OF PROVISIONS

Section 3 would give the public better insight into the number and value of samples, as well as what drug, device, or other medical supplies manufacturers give to health care providers for patient consumption. Specifically, section 3 amends SSA Section 1128G to add new reporting requirements for medical product samples under the Open Payments program. More specifically, beginning in 2023, manufacturers that provide a payment or transfer of value that is a product sample to covered recipients (or a recipient’s designee) would be required to electronically submit to the HHS Secretary certain information concerning the quantity and value of such samples, as well as additional data under specified circumstances. Manufacturers would be compelled to report aggregated data for the provided samples of each drug, device, biological, or medical supply. For purposes of the provision, product samples would be those that are not intended to be sold and are for patient use.

Additionally, the Open Payments website is required to display the total amount and total value of all samples provided to all covered recipients, and the name of covered drugs or other medical products, as applicable.

Section 3 also requires some of the information provided to the HHS Secretary to be reported separately to the Secretary of Treasury. Specifically, each manufacturer is required to report to the Secretary of Treasury the total value of all public samples it provided to covered recipients, as well as the portion of that amount for which an income tax deduction as an ordinary and necessary business expense was claimed by the manufacturer.

Nothing in this provision prevents drug and device manufacturers from continuing to provide free samples, nor does it add any new burdens to providers under the Open Payments Program. It only requires the disclosure of the total value and quantity of these samples.

#### EFFECTIVE DATE

The effective date of Section 3 is January 1, 2023.

<sup>41</sup> Medicare Payment Advisory Committee, *Report to Congress—Medicare and the Healthcare Delivery System: An Overview of the Medical Device Industry*. (June 2017) <http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf>.

## C. SECTION 4—ANALYSIS AND REPORT ON INPATIENT HOSPITAL DRUG COSTS

### CURRENT LAW

Under Medicare Part A, HHS pays most hospitals a pre-determined, per-discharge payment using a prospective payment system (or PPS) for covered inpatient services furnished to Medicare beneficiaries.<sup>42</sup> This PPS payment generally includes all inpatient hospital services that are furnished during an inpatient hospital stay, including drugs and biologicals ordinarily furnished by the hospital for the care and treatment of inpatients. Medicare PPS payments for drugs made up about 16 percent of total Medicare spending for pharmaceuticals in 2016.<sup>43</sup>

Although Part A payments for hospital inpatient drugs and biologicals are generally bundled into the PPS payment, there are exceptions for certain qualifying new, high-cost medical services or technologies including drugs, hemophilia clotting factors, and certain vaccines.<sup>44</sup>

### REASONS FOR CHANGE

Drug prices are skyrocketing across the health care sector with scrutiny focused on outpatient—and not inpatient—costs. Yet, because Medicare typically pays for inpatient prescription drugs on a bundled basis, little information is known about the costs of individual drugs in this setting because hospitals do not report the individual drug costs on their cost reports. This provision requires the Secretary of HHS to conduct a study to submit to Congress on inpatient (Medicare Part A) drug costs, including trends in the use of inpatient drugs by hospital type and an analysis of potential limitations in reporting such costs on the Medicare Cost Reports.

### EXPLANATION OF PROVISIONS

This provision requires the HHS Secretary to submit a report to the Committee on Ways and Means and the Senate Committee on Finance by January 1, 2021 regarding drug cost trends in the hospital inpatient setting. The report would include Medicare spending and inpatient drug cost and utilization trends by hospital characteristics such as hospital size, urban or rural location, teaching hospital status, and other hospital characteristics as determined by the HHS Secretary. The report is also required to address the effect of drug shortages on inpatient services. The HHS Secretary is authorized to conduct hospital surveys, and to use existing sources such as cost report data, or other data as determined appropriate. Section 4 would transfer \$3 million from the Hospital Insurance (Medicare Part A) Trust Fund to the HHS Secretary to carry out Section 4.

<sup>42</sup> Center for Medicare and Medicaid Services, *Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services Covered Under Part A,"* Section 30. (Rev. March 10, 2017) <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf>.

<sup>43</sup> MedPAC, *Overview: Medicare Drug Spending*, p. 7. (June 16, 2016) <http://medpac.gov/docs/default-source/fact-sheets/overview-of-medicare-drug-spending.pdf?sfvrsn=0>. Medicare also covered drugs under Part A through Medicare Advantage plans (Part C) which provide coverage for some Part A and Part B services.

<sup>44</sup> Center for Medicare and Medicaid Services, *Medicare Claims Policy Manual, Chapter: Inpatient Patient Billing*, Section 30 (Rev. October 26, 2018) <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>.

## EFFECTIVE DATE

The effective date of Section 4 is the date of enactment; while the study is required to be transmitted to Congress no later than January 1, 2021.

## D. SECTION 5—PUBLIC DISCLOSURE OF DRUG DISCOUNTS

## CURRENT LAW

Health plans typically contract with, or own, PBMs that perform a range of services including designing health plan formularies, creating lists of covered drugs; setting up contracted networks of retail pharmacies that dispense drugs to health plan enrollees for set reimbursement, and negotiating drug price concessions from pharmaceutical manufacturers—including up-front discounts or rebates after the point of sale. PBMs generally set prices for drugs, but in some cases PBMs dispense drugs from their own mail-order or specialty pharmacies.

PBM contract terms, and information about net drug prices negotiated by PBMs, generally are confidential due to market competition considerations. Some states have enacted legislation requiring health insurers and PBMs serving the commercial market to report aggregate information about drug price concessions.<sup>45</sup> In the Medicare Part D program, private insurers that offer Part D plans must report price data to the HHS Secretary to allow for benefit administration.<sup>46</sup> Much of the information is confidential, but the HHS Secretary is authorized to conduct periodic audits to protect against fraud and abuse and to ensure proper program disclosures and accounting.

As part of the 2010 Patient Protection and Affordable Care Act (ACA, P.L. 111–148, as amended), Congress required PBMs and health payers to report additional data about prescription drug sales and prices for Part D plans and Qualified Health Plans (QHPs) sold on state ACA insurance exchanges. QHPs are individual health insurance plans that undergo an additional HHS certification process, compared to other plans in the non-group market.<sup>47</sup>

Under the ACA provisions, SSA Section 1150A, a health plan or PBM that manages prescription drug coverage for a Part D plan or QHP, must report the following information to the HHS Secretary for a contract year:<sup>48</sup>

- The percentage of prescriptions provided through retail pharmacies as compared to mail order pharmacies.
- The percentage of prescriptions for which a generic drug was available and dispensed by a pharmacy, broken down by pharmacy type: mail order pharmacies, independent pharmacies, supermarket pharmacies, and mass merchandiser pharmacies.
- The aggregate amount of rebates, discounts, or price concessions (excluding certain bona fide service fees), negotiated

<sup>45</sup> National Academy for State Health Policy, *State Laws Help Spur Congressional Action on Drug Prices*. (February 19, 2019) <https://nashp.org/state-laws-help-spur-congressional-action-on-drug-prices/>.

<sup>46</sup> 42 C.F.R. § 423.104(g)(3).

<sup>47</sup> 42 U.S.C. § 18021.

<sup>48</sup> 42 C.F.R. § 423.514(d); 45 C.F.R. § 156.295.

by a PBM under a health plan that are attributable to patient utilization under the plan; the aggregate amount of rebates, discounts, or price concessions passed through by the PBM to a plan sponsor; and the total number of dispensed prescriptions.

- The aggregate amount of the difference between what a health plan pays a PBM, and what a PBM pays retail pharmacies, mail order pharmacies, and the total prescriptions dispensed.

The reported data are confidential and may not be disclosed by the HHS Secretary or by a plan receiving the information from a PBM, with limited exceptions. The HHS Secretary may disclose information—in a form that does not disclose the identity of a PBM or health plan, or prices charged for individual drugs—to administer certain provisions of the ACA, to administer Part D, or for review by the Government Accountability Office (GAO) or CBO. PBMs and health plans that do not comply with the provisions or that provide false information are subject to penalties.

#### REASONS FOR CHANGE

This provision requires the Secretary of HHS to post on the public HHS website the aggregate rebates and discounts PBMs receive from drug manufacturers, by class of drug. While PBMs already report this information to the Secretary under current law, transparency will help ensure that all plans, payers, and consumers have information to better understand how PBMs work and whether the discounts they achieve get passed on to lower costs. While PBMs negotiate lower drug prices through rebates, consumers still pay coinsurance off the list price, not the price the PBM negotiates—meaning that consumer costs remain high. Rebates can be used to lower patient premiums but policymakers do not understand if the increase in drug prices and patient cost-sharing is offset by any decrease in patient premiums.

With more transparency into the discounts PBMs achieve on different classes of drugs, insurance companies and large purchasers will be able to better evaluate PBM services and select PBMs that get the best discounts on the medicines their consumers use most. This policy could also help policymakers develop strategies to ensure lower drug prices and premiums.

This public reporting will not reveal proprietary information—it simply requires that the Secretary posts to a public website *aggregate* information that the PBMs already report. Reporting rebates and discounts in the aggregate (i.e., across PBMs) would be insufficient for policymakers and consumers to understand the types of discounts PBMs receive and the way those rebates impact health care costs.

#### EXPLANATION OF PROVISIONS

This provision would amend SSA Section 1150A to require the HHS Secretary to publicly release data on PBM-negotiated rebates, discounts, and other price concessions, as well as information on generic drug dispensing rates. Starting in 2020, the HHS Secretary would post aggregate data on the HHS website. The data, to be provided with a one-year lag, would be displayed in a way that

would prevent disclosure of price information about individual drugs or health plans. The HHS Secretary would be allowed to make information available about specific drug classes, if the HHS Secretary determined that the class contained a sufficient number of drugs to ensure confidentiality of proprietary information and did not allow for identification of individual drugs or health plans.

#### EFFECTIVE DATE

The effective date of Section 5 is January 1, 2020.

#### E. SECTION 6—REQUIRING CERTAIN MANUFACTURERS TO REPORT DRUG PRICING INFORMATION WITH RESPECT TO DRUGS UNDER THE MEDICARE PROGRAM

##### CURRENT LAW

In general, as a condition of participation in the Medicaid drug rebate program (MDRP), prescription drug and biological manufacturers are required to report certain drug price information to the HHS Secretary quarterly.<sup>49</sup> The MDRP agreement also requires drug and biological manufacturers to provide discounts to other federal programs.<sup>50</sup> The drug price information required from MDRP-participating drug manufacturers includes Medicaid “best price,” the average manufacturer price (AMP), the average sales price (ASP), and, in some situations, WAC.<sup>51</sup>

Best price and AMP are used in determining the amount of statutory rebates drug and biological manufacturers owe for a drug during a rebate period. ASP and WAC are used in determining Medicare Part B drug payments to providers.<sup>52</sup> The HHS Secretary is authorized to use the required price information to administer the programs but otherwise is prohibited from disclosing individual drug price information or making it public.<sup>53</sup>

Medicare covers most drugs under Medicare Part D, but some drugs are only available when administered by a physician under Medicare Part B. For Part B drugs, providers buy the appropriate drug and then are paid by Medicare after the drug is administered to a beneficiary. Even though drug manufacturers are required to submit timely ASP information for each Part B drug so those prices can be used to calculate what Medicare will pay providers for drugs, some drug manufacturers fail to submit each drug’s ASP or fail to submit the ASP within the specified time.<sup>54</sup> In addition, some drug and biological manufacturers do not participate in the MDRP and as a result are not required to submit the ASP for their products.<sup>55</sup>

<sup>49</sup> Manufacturer Provision of Price Information: 42 U.S.C. § 1396r–8.

<sup>50</sup> The Veterans Health Administration, the Coast Guard, Department of Defense, the Public Health Service Act (Section 340B Drug Pricing Program), and other federal agencies [Requirement for a Rebate Agreement, 42 U.S.C. § 1396r–8].

<sup>51</sup> Best Price Defined, Average manufacturer price (AMP): 42 U.S.C. § 1396r–8; Manufacturers Average Sales Price: 42 U.S.C. § 1395w–3a.

<sup>52</sup> Use of Average Sales Price Methodology: 42 U.S.C. § 1395w–3a.

<sup>53</sup> Confidentiality of Price Information: 42 U.S.C. § 1396r–8.

<sup>54</sup> Department of Health and Human Services Office of Inspector General, *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*: OEI-12-13 00040 (July 2014).

<sup>55</sup> *Ibid.*

## REASONS FOR CHANGE

This provision would make ASP data more accurate by requiring all manufacturers of drugs covered by Medicare Part B to report ASP data to the Secretary, mirroring the requirements and enforcement mechanism to which drug manufacturers with Medicaid agreements are currently subject. This provision is a commonsense policy recommended by a number of federal agencies: MedPAC, the GAO, the HHS Office of Inspector General (OIG), and the Administration in the fiscal year (FY) 2019 and 2020 President’s budgets. According to MedPAC:

“Failing to report ASPs can impact prices for Part B drugs in several ways. For drugs with partially complete ASP data—that is, drugs for which some manufacturers report ASPs but others do not—payment rates based on only the reported ASP data might not reflect average prices of all manufacturers accurately. For drugs with no ASP data—that is, drugs for which no manufacturer reports ASPs—CMS might resort to pricing drugs using alternative and potentially inflated measures of price such as WACs.”

## EXPLANATION OF PROVISIONS

This provision would amend SSA Section 1847A to require drug and biological manufacturers that do not participate in the MDRP, but have products that are separately payable under Medicare Part B, to report specified Medicare Part B drug price information to the HHS Secretary beginning January 1, 2020. The reported price information would be subject to audit by the HHS OIG.

Section 6 would authorize the HHS Secretary, when necessary, to survey wholesalers and drug and biological manufacturers that directly distribute Medicare Part B drugs to verify specified price information. The HHS Secretary would be authorized to impose a not-to-exceed \$100,000 CMP on drug manufacturers or drug suppliers if they refused a request from the HHS Secretary to provide price information or knowingly provided false information about charges or prices in connection with a verification survey. In addition, the HHS Secretary would be authorized to impose additional CMPs applicable under federal statute.

The information that this provision requires drug manufacturers or wholesalers to report would be kept confidential, and the HHS Secretary would be prohibited from disclosing that information in a form that identifies a specific manufacturer, wholesaler, or the drug prices charged except as necessary for GAO and CBO to review the information.

The HHS Secretary would be required to submit a report to Congress by January 1, 2021, that assesses the accuracy of the Medicare Part B ASP information submitted by drug and biological manufacturers. The report would be required to include recommendations on how to improve the accuracy of the ASP information.

## EFFECTIVE DATE

The effective date of Section 6 is January 1, 2020.

### III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 2113, “Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act of 2019” on April 9, 2019.

The Amendment in the Nature of a Substitute was agreed to by a roll call vote of 40 yeas to 0 nays. The vote was as follows.

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
MR. NEAL .....	X	.....	.....	MR. BRADY .....	X	.....	.....
MR. LEWIS .....	X	.....	.....	MR. NUNES .....	X	.....	.....
MR. DOGGETT .....	X	.....	.....	MR. BUCHANAN .....	X	.....	.....
MR. THOMPSON .....	X	.....	.....	MR. SMITH (NE) .....	X	.....	.....
MR. LARSON .....	X	.....	.....	MR. MARCHANT .....	X	.....	.....
MR. BLUMENAUER .....	.....	.....	.....	MR. REED .....	X	.....	.....
MR. KIND .....	X	.....	.....	MR. KELLY .....	X	.....	.....
MR. PASCARELL .....	X	.....	.....	MR. HOLDING .....	X	.....	.....
MR. DAVIS .....	X	.....	.....	MR. SMITH (MO) .....	X	.....	.....
MS. SANCHEZ .....	.....	.....	.....	MR. RICE .....	X	.....	.....
MR. HIGGINS .....	X	.....	.....	MR. SCHWEIKERT .....	X	.....	.....
MS. SEWELL .....	X	.....	.....	MS. WALORSKI .....	X	.....	.....
MS. DELBENE .....	X	.....	.....	MR. LAHOOD .....	X	.....	.....
MS. CHU .....	X	.....	.....	MR. WENSTRUP .....	X	.....	.....
MS. MOORE .....	X	.....	.....	MR. ARRINGTON .....	X	.....	.....
MR. KILDEE .....	X	.....	.....	MR. FERGUSON .....	X	.....	.....
MR. BOYLE .....	X	.....	.....	MR. ESTES .....	X	.....	.....
MR. BEYER .....	X	.....	.....				
MR. EVANS .....	X	.....	.....				
MR. SCHNEIDER .....	X	.....	.....				
MR. SUOZZI .....	X	.....	.....				
MR. PANETTA .....	X	.....	.....				
MS. MURPHY .....	X	.....	.....				
MR. GOMEZ .....	X	.....	.....				
MR. HORSFORD .....	X	.....	.....				

H.R. 2113 was ordered favorably reported to the House of Representatives by voice vote (with a quorum being present).

### IV. BUDGET EFFECTS OF THE BILL

#### A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the bill, H.R. 2113, as reported. The Committee agrees with the estimate prepared by CBO, which is included below.

#### B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET  
OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, June 24, 2019.*

Hon. RICHARD NEAL,  
*Chairman, Committee on Ways and Means,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2113, the Prescription Drug STAR Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Lara Robillard and Rebecca Yip.

Sincerely,

PHILLIP L. SWAGEL,  
*Director.*

Enclosure.

At a Glance			
H.R. 2113, Prescription Drug STAR Act			
As ordered reported by the House Committee on Ways and Means on April 9, 2019			
By Fiscal Year, Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	-677	-1,727
Revenues	0	0	0
Deficit Effect	0	-677	-1,727
Spending Subject to Appropriation (Outlays)	0	0	0
Statutory pay-as-you-go procedures apply?	Yes	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

The bill would

- Require prescription drug manufacturers to provide information to the Secretary of Health and Human Services (HHS) about the factors (including expenditures and revenue items) that contribute to increases in drug prices that exceed thresholds established in the bill
- Require drug manufacturers to disclose information about samples provided to physicians
- Direct the Secretary of HHS to study spending on drugs furnished in hospitals and to publish data about prices and discounts under Medicare Part D
- Require drug manufacturers to report the sales prices used to calculate payments for drugs covered under Medicare Part B



Estimated budgetary effects would primarily stem from

- Requiring drug manufacturers to report prices used to calculate Medicare payment rates for their products administered in physicians' offices and hospital outpatient departments
- Appropriating \$3 million to the Secretary of HHS to study hospitals' drug costs

Areas of significant uncertainty include accurately projecting

- The ways that new disclosure requirements would affect the behavior of drug manufacturers or medical providers
- Drug manufacturers' responses to possible changes in the regulatory status of certain products

Bill summary: H.R. 2113 would require prescription drug manufacturers to submit information—including data about drug prices, price increases, and distribution of samples—to the Department of Health and Human Services. In addition, the bill would direct the Secretary of HHS to publish information about prescription drug prices and discounts.

Estimated Federal cost: The estimated budgetary effect of H.R. 2113 is shown in Table 1. The costs of the legislation fall within budget function 570 (Medicare).

TABLE 1.—ESTIMATED BUDGETARY EFFECTS OF H.R. 2113

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2019–2024	2019–2029
	By fiscal year, millions of dollars—												
	Increases or Decreases (–) in Direct Spending												
Require Manufacturers to Report Drug Pricing With Respect to Drugs Under the Medicare Program:													
Estimated Budget Authority .....	0	–20	–150	–170	–170	–170	–190	–200	–210	–230	–220	–680	–1,730
Estimated Outlays .....	0	–20	–150	–170	–170	–170	–190	–200	–210	–230	–220	–680	–1,730
Report on Inpatient Hospital Drug Costs:													
Budget Authority .....	0	3	0	0	0	0	0	0	0	0	0	3	3
Estimated Outlays .....	0	3	0	0	0	0	0	0	0	0	0	3	3
	Total Changes in Direct Spending												
Estimated Budget Authority .....	0	–17	–150	–170	–170	–170	–190	–200	–210	–230	–220	–677	–1,727
Estimated Outlays .....	0	–17	–150	–170	–170	–170	–190	–200	–210	–230	–220	–677	–1,727

Components may not sum to totals because of rounding.

Basis of estimate: H.R. 2113 would increase the information available to the Secretary of HHS, researchers, and the general public about prescription drug prices and spending. For this estimate, CBO assumes that the bill will be enacted near the end of fiscal year 2019.

Direct spending: Two provisions of H.R. 2113 would affect direct spending.

*Require manufacturers to report drug pricing with respect to drugs under the Medicare program*

The bill would enhance reporting requirements for manufacturers of products covered under Part B. CMS uses such data to calculate average sales prices (ASPs)—the average prices at which manufacturers sell their products. ASPs are the basis of Medicare’s payments for infused and injected drugs. When ASP data are not available for a drug—for example, when it is first marketed and no sales have occurred—Medicare’s payments usually are based on the Wholesale Acquisition Cost (WAC). WACs are generally higher than ASPs. The bill would make changes, as described below, which would have the effect of establishing the ASP for some drugs that are currently paid for based on the WAC. CBO estimates those changes would reduce federal spending by \$1.7 billion over the 2019–2029 period.

To ensure full reporting of ASP data to the Secretary and thus enable ASP-based payment, manufacturers with drug rebate agreements (as required for drugs that are covered by state Medicaid programs) also must report their ASP data to CMS, with some exceptions. In particular, under current law, the Medicaid rebate applies to products that are approved as drugs under the Federal Food, Drug, and Cosmetic Act. Among the products that do not require Medicaid rebate agreements and that are therefore exempt from ASP reporting are those that incorporate hyaluronic acid, which is used to treat osteoarthritis of the knee. The Food and Drug Administration (FDA) regulates such products as medical devices, not as drugs, although Medicare pays for them as drugs. Medicare Part B currently covers several such products. Recently, some manufacturers of those products stopped reporting ASP data to CMS. As a result, Medicare is paying for a subset of hyaluronic acid products based on their higher WACs.<sup>1</sup>

CBO analyzed data from the CMS website concerning payment for and use of hyaluronic acid products, along with information on the difference between their ASPs (when they were available) and WACs. CBO estimates that requiring manufacturers to report ASP data would reduce direct spending by about \$3.6 billion over the 2019–2029 period, a result of lower, ASP-based benchmarks for Part B drug payment.

However, in December 2018, the FDA published a notice in which it indicated that it is considering regulating hyaluronic acid products as drugs, not as devices.<sup>2</sup> The implications of that notice

<sup>1</sup>For more information, see Medicare Payment Advisory Commission, The MedPAC Blog, “Improving Medicare’s payment for Part B drugs: Requiring pharmaceutical manufacturer reporting of sales price data,” June 14, 2019, <http://www.medpac.gov/-blog/-reporting-reporting-of-sales-price-data/2019/06/14/payment-for-part-b-drugs>

<sup>2</sup>See Food and Drug Administration, “Intent to Consider the Appropriate Classification of Hyaluronic Acid Intra-articular Products Intended for the Treatment of Pain in Osteoarthritis

for products currently on the market are unclear. It is possible that current products would be considered drugs and require rebate agreements, thus triggering mandatory ASP reporting. Accounting for the possibility that the FDA could decide to regulate those products as drugs, CBO has lowered its estimated savings of this bill to \$1.7 billion over the 2019–2029 period, to reflect a 50 percent probability that the hyaluronic acid products would come to be regulated as drugs under current law.

*Report on inpatient hospital drug costs*

The bill also would appropriate \$3 million to the Secretary of HHS to study spending for drugs used by hospital inpatients. CBO estimates that implementing that provision would increase direct spending by \$3 million over the 2019–2029 period (see Table 1).

*Reporting and penalties*

Other provisions of the bill would require other reporting by pharmaceutical manufacturers:

- Drug manufacturers would have to explain increases in drug prices that exceed a threshold amount established in the bill. The manufacturer also would be obliged to report how much it had spent on manufacturing the drug, its overall investments in research and development, and its net profits for the drug from the time of introduction to the market. Failure to submit that information could subject the manufacturer to a civil monetary penalty of \$10,000 for each day that the manufacturer did not report.
- The bill would require drug manufacturers to report data about drug samples they supply to providers to enable providers to start patients on drugs and to save patients from initial costs and pharmacy visits.
- Under current law, health plans and pharmacy benefit managers that participate in Medicare Part D or in the health insurance marketplaces established under the Affordable Care Act (ACA) must report to the Secretary on the aggregated amounts they negotiate in discounts, rebates, and price concessions. The ACA requires the Secretary to keep that information confidential. H.R. 2113 would direct the Secretary to make that information public after two years, with restrictions on plan- or drug-specific information.

Requiring manufacturers to report on drug samples and discounts would not affect Medicare spending or spending by other payers. Although the legislation would impose civil monetary penalties on manufacturers who fail to meet new reporting requirements, CBO expects that all manufacturers would meet reporting requirements. Therefore, CBO estimates that no penalties would be collected and enacting the bill would have no budgetary effect.<sup>3</sup>

Spending subject to appropriation: Many of the activities required by H.R. 2113 would add to the responsibilities of the Secretary of HHS in managing Medicare and in overseeing the health

of the Knee Based on Scientific Evidence,” *Federal Register* (December 18, 2018), vol. 83, no. 242, pp. 64844–64845, <https://go.usa.gov/xyx3Q>.

<sup>3</sup>In general, however, such penalties, once collected, may be spent without further appropriation action. As a result, CBO usually estimates new mandatory outlays in an amount that offsets those revenues.

insurance marketplaces. Funding for most program management activities is subject to appropriation. In CBO's judgment, the new activities required by H.R. 2113 would not significantly increase the department's workload and thus implementing the bill would not result in significant additional discretionary costs.

Uncertainty: It is possible that the information made available under H.R. 2113 could change the behavior of drug manufacturers or medical providers in ways that CBO did not anticipate. For example, requiring manufacturers to report their sample distributions could make them less likely to provide samples, or it could make providers less willing to accept them. However, CBO estimates that any such behavioral effect would be small enough to have no significant budgetary effect.

As noted above, the FDA regulatory status of certain products is uncertain, and CBO's estimate reflects the possibility that their classification could change in such a way that manufacturers would be required to report ASP data rather than WAC data. If, however, FDA regulations do not change, savings would probably be higher than CBO has estimated.

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in Table 1.

Increase in long-term deficits: None.

Mandates: H.R. 2113 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). Participation in Medicare is voluntary for private entities. Therefore, the reporting requirements in the bill arising from participation in those programs would not constitute private-sector mandates as defined in UMRA.

Estimate prepared by: Federal costs: Lara Robillard and Rebecca Yip; Mandates: Andrew Laughlin.

Estimate reviewed by: Tom Bradley, Chief, Health Systems and Medicare Cost Estimates Unit; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa Gullo, Assistant Director for Budget Analysis.

## **V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE**

### **A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS**

With respect to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

### **B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES**

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for which any measure authorizes funding is required.

### C. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

### D. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

### E. DUPLICATION OF FEDERAL PROGRAMS

On a bill that establishes or reauthorizes a federal program. In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report to Congress pursuant to section 21 of Public Law 111–139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant section 6104 of title 31, United States Code.

### F. HEARINGS

In compliance with Sec. 103(i) of H. Res. 6 (116th Congress) the following hearings were used to develop or consider H.R. 2113:

- (1) Committee on Ways and Means Hearing on “The Cost of Rising Prescription Drug Price,” held on February 12, 2019.
- (2) Committee on Ways and Means Subcommittee on Health Hearing on “Promoting Competition to Lower Medicare Drug Prices,” held on March 7, 2019.

## VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

### CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics,

and existing law in which no change is proposed is shown in roman):

## SOCIAL SECURITY ACT

\* \* \* \* \*

### TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

\* \* \* \* \*

#### PART A—GENERAL PROVISIONS

\* \* \* \* \*

#### SEC. 1128G. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

##### (a) TRANSPARENCY REPORTS.—

##### (1) PAYMENTS OR OTHER TRANSFERS OF VALUE.—

(A) IN GENERAL.—On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

- (i) The name of the covered recipient.
- (ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.
- (iii) The amount of the payment or other transfer of value.
- (iv) The dates on which the payment or other transfer of value was provided to the covered recipient.
- (v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—
  - (I) cash or a cash equivalent;
  - (II) in-kind items or services;
  - (III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
  - (IV) any other form of payment or other transfer of value (as defined by the Secretary).
- (vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—
  - (I) consulting fees;
  - (II) compensation for services other than consulting;
  - (III) honoraria;
  - (IV) gift;
  - (V) entertainment;

- (VI) food;
- (VII) travel (including the specified destinations);
- (VIII) education;
- (IX) research;
- (X) charitable contribution;
- (XI) royalty or license;
- (XII) current or prospective ownership or investment interest;
- (XIII) direct compensation for serving as faculty or as a speaker for a medical education program;
- (XIV) grant; or
- (XV) any other nature of the payment or other transfer of value (as defined by the Secretary).

(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

(B) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(2) PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (1)(A), on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

(A) The dollar amount invested by each physician holding such an ownership or investment interest.

(B) The value and terms of each such ownership or investment interest.

(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, “physician” shall be substituted for “covered recipient” each place it appears.



(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

(3) *CERTAIN PRODUCT SAMPLES.—*

(A) *IN GENERAL.—In addition to the requirements under paragraphs (1)(A) and (2), on the 90th day of each calendar year (beginning with 2023), any applicable manufacturer that provides a payment or other transfer of value that is a product sample described in subparagraph (B) to any covered recipient (or to an entity or individual at the request of, or designated on behalf of, such a covered recipient) shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information (aggregated per each drug, device, biological, or medical supply, as applicable) with respect to the preceding calendar year:*

*(i) The total quantity of all such payments or other transfers of value provided to all covered recipients.*

*(ii) The total value of all such payments or other transfers of value provided to all covered recipients.*

*(iii) If applicable, information described in clauses (vii) and (viii) of paragraph (1)(A) with respect to such a payment or other transfer of value.*

(B) *PRODUCT SAMPLE DESCRIBED.—For purposes of subparagraph (A), a product sample described in this subparagraph is a product sample that is not intended to be sold and is intended for patient use.*

(b) *PENALTIES FOR NONCOMPLIANCE.—*

(1) *FAILURE TO REPORT.—*

(A) *IN GENERAL.—Subject to subparagraph (B) except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.*

(B) *LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed \$150,000.*

(2) *KNOWING FAILURE TO REPORT.—*

(A) *IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than \$10,000, but not more than \$100,000, for each payment or other transfer of value or ownership or*

investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed \$1,000,000.

(3) USE OF FUNDS.—Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

(c) PROCEDURES FOR SUBMISSION OF INFORMATION AND PUBLIC AVAILABILITY.—

(1) IN GENERAL.—

(A) ESTABLISHMENT.—Not later than October 1, 2011, the Secretary shall establish procedures—

(i) for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary under subsection (a); and

(ii) for the Secretary to make such information submitted available to the public.

(B) DEFINITION OF TERMS.—The procedures established under subparagraph (A) shall provide for the definition of terms (other than those terms defined in subsection (e)), as appropriate, for purposes of this section.

(C) PUBLIC AVAILABILITY.—Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that—

(i) is searchable and is in a format that is clear and understandable;

[(ii) contains] *(ii)(I) with respect to information that is not information submitted under paragraph (3) of subsection (a), contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply*], *as applicable; and*

*(II) with respect to information submitted under paragraph (3) of subsection (a), contains information that is presented by the name of the applicable manu-*

*facturer, the total amount of all payments or other transfers of value described in such paragraph provided to all covered recipients, the total value of all such payments or other transfers of value provided to all covered recipients, and the name of the covered drug, device, biological, or medical supply, as applicable;*

(iii) contains information that is able to be easily aggregated and downloaded;

(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

(v) contains background information on industry-physician relationships;

(vi) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (E)(i), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

(vii) contains any other information the Secretary determines would be helpful to the average consumer;

(viii) in the case of information made available under this subparagraph prior to January 1, 2022, does not contain the National Provider Identifier of the covered recipient, and

(ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

(D) CLARIFICATION OF TIME PERIOD FOR REVIEW AND CORRECTIONS.—In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available to the public in accordance with the dates described in the matter preceding clause (i) in subparagraph (C).

(E) DELAYED PUBLICATION FOR PAYMENTS MADE PURSUANT TO PRODUCT RESEARCH OR DEVELOPMENT AGREEMENTS AND CLINICAL INVESTIGATIONS.—

(i) IN GENERAL.—In the case of information submitted under subsection (a) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applica-

ble manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under subparagraph (A)(ii) shall provide that such information is made available to the public on the first date described in the matter preceding clause (i) in subparagraph (C) after the earlier of the following:

(I) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(II) Four calendar years after the date such payment or other transfer of value was made.

(ii) CONFIDENTIALITY OF INFORMATION PRIOR TO PUBLICATION.—Information described in clause (i) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

(2) CONSULTATION.—In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

(d) ANNUAL REPORTS AND RELATION TO STATE LAWS.—

(1) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

(B) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

(2) ANNUAL REPORTS TO STATES.—Not later than September 30, 2013 and on June 30 of each calendar year thereafter, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

(3) RELATION TO STATE LAWS.—

(A) IN GENERAL.—In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient (as defined in subsection (e)) on or after January 1, 2012, subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the type of information (as described in subsection (a)) regarding such payment or other transfer of value.

(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Subparagraph (A) shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information—

(i) not of the type required to be disclosed or reported under this section;

(ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection;

(iii) by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (e)); or

(iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

(C) Nothing in subparagraph (A) shall be construed to limit the discovery or admissibility of information described in such subparagraph in a criminal, civil, or administrative proceeding.

(4) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

(e) DEFINITIONS.—In this section:

(1) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term “applicable group purchasing organization” means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(2) APPLICABLE MANUFACTURER.—The term “applicable manufacturer” means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(3) CLINICAL INVESTIGATION.—The term “clinical investigation” means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(4) COVERED DEVICE.—The term “covered device” means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(5) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term “covered drug, device, biological, or medical

supply” means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(6) COVERED RECIPIENT.—

(A) IN GENERAL.—Except as provided in subparagraph

(B), the term “covered recipient” means the following:

- (i) A physician.
- (ii) A teaching hospital.
- (iii) A physician assistant, nurse practitioner, or clinical nurse specialist (as such terms are defined in section 1861(aa)(5)).
- (iv) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)).
- (v) A certified nurse-midwife (as defined in section 1861(gg)(2)).

(B) EXCLUSION.—Such term does not include a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, or certified nurse-midwife who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

(7) EMPLOYEE.—The term “employee” has the meaning given such term in section 1877(h)(2).

(8) KNOWINGLY.—The term “knowingly” has the meaning given such term in section 3729(b) of title 31, United States Code.

(9) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term “manufacturer of a covered drug, device, biological, or medical supply” means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

(10) PAYMENT OR OTHER TRANSFER OF VALUE.—

(A) IN GENERAL.—The term “payment or other transfer of value” means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

(B) EXCLUSIONS.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

- (i) A transfer of anything the value of which is less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds \$100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as

the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(ii) **Product samples** *Except for purposes of paragraph (3) of subsection (a), product samples* that are not intended to be sold and are intended for patient use.

(iii) Educational materials that directly benefit patients or are intended for patient use.

(iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(vii) Discounts (including rebates).

(viii) In-kind items used for the provision of charity care.

(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

(x) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(xi) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.

(xii) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

(11) **PHYSICIAN.**—The term “physician” has the meaning given that term in section 1861(r).

\* \* \* \* \*

**SEC. 1128L. DRUG MANUFACTURER PRICE TRANSPARENCY.**

(a) *IN GENERAL.*—With respect to each year, beginning with 2021, the Secretary shall, at least once during such year, determine if there is a triggered **SPIKE** increase (in accordance with subsection (b)) with respect to an applicable drug (as defined in subsection (f)(1)). If the Secretary determines, with respect to a year, there is such an increase with respect to an applicable drug, the manufacturer of the applicable drug shall submit to the Secretary the justification described in subsection (c), subject to subsection (b)(4), for

each such triggered *SPIKE* increase in accordance with the timing described in subsection (d)).

(b) **TRIGGERED SPIKE INCREASE.**—

(1) **IN GENERAL.**—A triggered *SPIKE* increase occurs, with respect to an applicable drug and year (beginning with 2021 and referred to in this paragraph as the “applicable year”), in any of the following cases:

(A) If there is at least a 10 percent (or \$10,000) cumulative increase with respect to the wholesale acquisition cost (or alternative cost measure specified by the Secretary under paragraph (3)) of such drug during a calendar-year period beginning and ending within the lookback period that is the 5-year period preceding such applicable year.

(B) If there is at least a 25 percent (or \$25,000) cumulative increase with respect to the wholesale acquisition cost (or such alternative cost measure) of such drug during any three-calendar-year period beginning and ending within such lookback period.

(C) In the case of such a drug that is first covered under title XVIII with respect to such applicable year, if the estimated cost or spending under such title per individual or per user of such drug (as estimated by the Secretary) for such applicable year (or per course of treatment in such applicable year, as defined by the Secretary) is at least \$26,000.

(2) **INDEXING DOLLAR AMOUNTS.**—The dollar amounts applied under paragraph (1) for 2022 and each subsequent year shall be the dollar amounts specified in such paragraph for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year. If any amount established under paragraph (1), after application of this paragraph, for a year is not a multiple of \$10, it shall be rounded to the nearest multiple of \$10.

(3) **ALTERNATIVE TO WAC.**—The Secretary may, for purposes of making determinations under paragraph (1), in addition to using the wholesale acquisition cost for an applicable drug, use alternative cost measures of such drug, or use such alternative cost measure if the wholesale acquisition cost is not available.

(4) **EXCEPTION.**—A justification under subsection (c) shall not be required for a triggered *SPIKE* increase described in paragraph (1) of an applicable drug of a manufacturer if—

(A) there is any portion of the lookback period described in the respective subparagraph of such paragraph for such increase that is included within the lookback period for another triggered *SPIKE* increase (or combination of such increases) for which a justification is made under this section for such drug by such manufacturer; or

(B) such increase is less than the wholesale acquisition cost (or alternative cost measure specified by the Secretary under paragraph (3)) of such drug during the calendar-year period described in paragraph (1)(A) or the three-calendar-year period described in paragraph (1)(B), as applicable, for such increase, increased by the percentage increase in the consumer price index for all urban consumers



(all items; United States city average) for the 12-month period ending six months prior to the calendar-year period so described and for the 36-month period ending six months prior to the three-calendar-year period so described, respectively.

(5) *UNIT DETERMINATION.*—For purposes of determining the wholesale acquisition cost in carrying out this section, the Secretary shall determine a unit (such as a unit size) to apply.

(6) *PUBLIC POSTING.*—Beginning with respect to 2021, the Secretary shall publicly post on the Internet website of the Department of Health and Human Services—

(A) alternative percentages, dollar amounts, and lookback periods that, if applied under paragraph (1), would be projected to increase the number of applicable drugs for which a triggered SPIKE increase would occur for such year; and

(B) the number of applicable drugs for which a triggered SPIKE increase would occur for such year if such an alternative percentage, dollar amount, or period were applied for such year.

(c) *JUSTIFICATION DESCRIBED.*—

(1) *IN GENERAL.*—The justification described in this subsection, with respect to a triggered SPIKE increase described in subsection (b)(1) of an applicable drug of a manufacturer, is—

(A) all of the information described in paragraph (2);

(B) all of the information and supporting documentation described in paragraph (3), as applicable to the increase and drug; and

(C) a certification described in paragraph (4).

(2) *REQUIRED INFORMATION.*—For purposes of paragraph (1), the information described in this paragraph is the following:

(A) The individual factors that have contributed to the increase in the wholesale acquisition cost.

(B) An explanation of the role of each factor in contributing to such increase.

(3) *INFORMATION AS APPLICABLE.*—For purposes of paragraph (1), the information and supporting documentation described in this paragraph is the following, as applicable to the increase of the drug:

(A) Total expenditures of the manufacturer on—

(i) materials and manufacturing for such drug;

(ii) acquiring patents and licensing for each drug of the manufacturer; and

(iii) costs to purchase or acquire the drug from another company, if applicable.

(B) The percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds.

(C) The total expenditures of the manufacturer on research and development for such drug.

(D) The total revenue and net profit generated from the applicable drug for each calendar year since drug approval.

(E) The total costs associated with marketing and advertising for the applicable drug.

(F) Additional information specific to the manufacturer of the applicable drug, such as—

(i) the total revenue and net profit of the manufacturer for the period of such increase, as determined by the Secretary;

(ii) metrics used to determine executive compensation;

(iii) total expenditures on—

(I) drug research and development; or

(II) clinical trials on drugs that failed to receive approval by the Food and Drug Administration; and

(iv) any additional information related to drug pricing decisions of the manufacturer.

(G) Any other relevant information and supporting documentation necessary to justify the triggering SPIKE increase.

(H) Any other relevant information and supporting documentation, as specified by the Secretary.

(4) CERTIFICATION.—For purposes of paragraph (1), the certification described in this paragraph is a certification, that all such information and documentation is accurate and complete, by one of the following:

(A) The chief executive officer of the manufacturer.

(B) The chief financial officer of the manufacturer.

(C) An individual who has delegated authority to sign for, and who reports directly to, such chief executive officer or chief financial officer.

(d) TIMING.—

(1) NOTIFICATION.—Not later than 60 days after the date on which the Secretary makes the determination that there is a triggering SPIKE increase with respect to an applicable drug, the Secretary shall notify the manufacturer of the applicable drug of such determination.

(2) SUBMISSION OF JUSTIFICATION.—Not later than 90 days after the date on which a manufacturer receives a notification under paragraph (1), subject to subsection (b)(4), the manufacturer shall submit to the Secretary the justification required under subsection (a), including a summary of such justification, in a form and manner specified by the Secretary. In specifying such form, with respect to the summary required under the previous sentence, the Secretary shall provide that such summary shall be in an easily understandable format, as specified by the Secretary, and shall permit the manufacturer to exclude proprietary information from such summary.

(3) POSTING ON INTERNET WEBSITE.—Not later than 30 days after receiving the complete justification under paragraph (2), the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the summary included for such justification.

(e) PENALTIES.—

(1) FAILURE TO SUBMIT TIMELY JUSTIFICATION.—If the Secretary determines that a manufacturer has failed to submit a justification as required under this section, including in accordance with the timing and form required, with respect to an applicable drug, the Secretary shall apply a civil monetary pen-

alty in an amount of \$10,000 for each day the manufacturer has failed to submit such justification as so required.

(2) *FALSE INFORMATION.*—Any manufacturer that submits a justification under this section that knowingly provides false information in such justification is subject to a civil monetary penalty in an amount not to exceed \$100,000 for each item of false information.

(3) *APPLICATION OF PROCEDURES.*—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). Civil monetary penalties imposed under this subsection are in addition to other penalties as may be prescribed by law.

(f) *DEFINITIONS.*—In this section:

(1) *APPLICABLE DRUG.*—

(A) *IN GENERAL.*—Subject to subparagraph (B), the term “applicable drug” means, with respect to a lookback period described in subsection (b)(1), a covered outpatient drug (as defined in paragraph (2) of section 1927(k), without application of paragraph (3) of such section) that is covered under title XVIII and is not a low cost drug.

(B) *EXCLUSION OF LOW COST DRUGS.*—For purposes of subparagraph (A), not later than January 1, 2021, the Secretary shall specify a threshold (such as a cost or spending threshold) for identifying (and shall identify) low cost drugs to be excluded from the definition of the term “applicable drug”, such as a drug that has a wholesale acquisition cost of less than \$10 per unit or less than \$100 in average estimated expenditures under title XVIII per individual per year or per user of such drug per year. For purposes of this section, a drug shall not be considered specified as a low cost drug for a lookback period described in subsection (b)(1) with respect to a year unless such drug is identified as being below the specified threshold for the entirety of the lookback period.

(2) *MANUFACTURER.*—The term “manufacturer” has the meaning given that term in section 1847A(c)(6)(A).

(3) *WHOLESALE ACQUISITION COST.*—The term “wholesale acquisition cost” has the meaning given that term in section 1847A(c)(6)(B).

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#### **SEC. 1150A. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.**

(a) *PROVISION OF INFORMATION.*—A health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan (in this section referred to as a “PBM”) that manages prescription drug coverage under a contract with—

(1) a PDP sponsor of a prescription drug plan or an MA organization offering an MA-PD plan under part D of title XVIII; or

(2) a qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act, shall provide the information described in subsection (b) to the Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with, at such times, and in such form and manner, as the Secretary shall specify.

(b) INFORMATION DESCRIBED.—The information described in this subsection is the following with respect to services provided by a health benefits plan or PBM for a contract year:

(1) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract.

(2) The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(3) The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(c) CONFIDENTIALITY.—Information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary (*other than as permitted under subsection (e)*) or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines to be necessary to carry out this section or part D of title XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(4) To States to carry out section 1311 of the Patient Protection and Affordable Care Act.

(d) PENALTIES.—The provisions of subsection (b)(3)(C) of section 1927 shall apply to a health benefits plan or PBM that fails to provide information required under subsection (a) on a timely basis or that knowingly provides false information in the same manner as

such provisions apply to a manufacturer with an agreement under that section.

(e) **PUBLIC AVAILABILITY OF CERTAIN INFORMATION.**—

(1) **IN GENERAL.**—*In order to allow the comparison of PBMs' ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions that are passed through to plan sponsors, beginning January 1, 2020, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information with respect to the second preceding calendar year provided to the Secretary on generic dispensing rates (as described in paragraph (1) of subsection (b) and information provided to the Secretary under paragraphs (2) and (3) of such subsection that, as determined by the Secretary, is with respect to each PBM.*

(2) **AVAILABILITY OF DATA.**—*In carrying out paragraph (1), the Secretary shall ensure the following:*

(A) **CONFIDENTIALITY.**—*The information described in such paragraph is displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions, with respect to an individual drug or an individual plan.*

(B) **CLASS OF DRUG.**—*The information described in such paragraph is made available by class of drug, using an existing classification system, but only if the class contains such number of drugs, as specified by the Secretary, to ensure confidentiality of proprietary information or other information that is prevented to be disclosed under subparagraph (A).*

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## **TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED**

\* \* \* \* \*

### **PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED**

\* \* \* \* \*

#### **USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY**

##### **SEC. 1847A. (a) APPLICATION.**—

(1) **IN GENERAL.**—Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1842(o)(1)(C) and that are furnished on or after January 1, 2005.

(2) **ELECTION.**—This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B for that section to apply instead of this section for the payment for drugs and biologicals.

##### **(b) PAYMENT AMOUNT.**—

(1) **IN GENERAL.**—Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological

(based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4); or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) SPECIFICATION OF UNIT.—

(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1927(b)(3)(A)(iii) or subsection (f)(2), as applicable.

(B) UNIT DEFINED.—In this section, the term “unit” means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) or subsection (f)(2), as applicable, determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer’s average sales price (as defined in subsection (c)); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) SINGLE SOURCE DRUG OR BIOLOGICAL.—The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) AVERAGE SALES PRICE.—The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals

furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) BASIS FOR PAYMENT AMOUNT.—The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) USE OF VOLUME-WEIGHTED AVERAGE SALES PRICES IN CALCULATION OF AVERAGE SALES PRICE.—

(A) IN GENERAL.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) or subsection (f)(2), as applicable, determined by—

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the manufacturer's average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) BILLING UNIT DEFINED.—For purposes of this subsection, the term “billing unit” means the identifiable quantity associated with a billing and payment code, as established by the Secretary.

(7) SPECIAL RULE.—Beginning with April 1, 2008, the payment amount for—

(A) each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of—

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of—

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(8) BIOSIMILAR BIOLOGICAL PRODUCT.—The amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(C) is the sum of—

(A) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and

(B) 6 percent of the amount determined under paragraph (4) for the reference biological product (as defined in subsection (c)(6)(I)).

(c) MANUFACTURER'S AVERAGE SALES PRICE.—

(1) IN GENERAL.—For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's "average sales price" means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of "best price" under section 1927(c)(1)(C)(i).

(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1927(c)(1)(C)(ii)(III), except as the Secretary may otherwise provide).

(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(4) PAYMENT METHODOLOGY IN CASES WHERE AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS UNAVAILABLE.—In the case of a drug or biological during an initial period (not to



exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—

(A) the wholesale acquisition cost; or

(B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

(5) FREQUENCY OF DETERMINATIONS.—

(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) UPDATES IN PAYMENT AMOUNTS.—The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

(6) DEFINITIONS AND OTHER RULES.—In this section:

(A) MANUFACTURER.—The term “manufacturer” means, with respect to a drug or biological, the manufacturer (as defined in section 1927(k)(5))**[.]**, *except that, for purposes of subsection (f)(2), the Secretary may, if the Secretary determines appropriate, exclude repackagers of a drug or biological from such term.*

(B) WHOLESALE ACQUISITION COST.—The term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(C) MULTIPLE SOURCE DRUG.—

(i) IN GENERAL.—The term “multiple source drug” means, for a calendar quarter, a drug for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) EXCEPTION.—With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) SINGLE SOURCE DRUG OR BIOLOGICAL.—The term "single source drug or biological" means—

(i) a biological; or

(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, "other than a vaccine" is deemed deleted from section 1927(k)(2)(B).

(H) BIOSIMILAR BIOLOGICAL PRODUCT.—The term "biosimilar biological product" means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act.

(I) REFERENCE BIOLOGICAL PRODUCT.—The term "reference biological product" means the biological product li-

censed under such section 351 that is referred to in the application described in subparagraph (H) of the biosimilar biological product.

(d) MONITORING OF MARKET PRICES.—

(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

(2) COMPARISON OF PRICES.—Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

(A) the widely available market price for such drugs and biologicals (if any); and

(B) the average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.

(3) LIMITATION ON AVERAGE SALES PRICE.—

(A) IN GENERAL.—The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) APPLICABLE THRESHOLD PERCENTAGE DEFINED.—In this paragraph, the term “applicable threshold percentage” means—

(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

(C) AUTHORITY TO ADJUST AVERAGE SALES PRICE.—If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

(i) the widely available market price for the drug or biological (if any); or

(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.

(4) CIVIL MONEY PENALTY.—

(A) **[IN GENERAL]** MISREPRESENTATION.—If the Secretary determines that a manufacturer has made a mis-

representation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to \$10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

*(B) FAILURE TO PROVIDE TIMELY INFORMATION.—If the Secretary determines that a manufacturer described in subsection (f)(2) has failed to report on information described in section 1927(b)(3)(A)(iii) with respect to a drug or biological in accordance with such subsection, the Secretary shall apply a civil money penalty in an amount of \$10,000 for each day the manufacturer has failed to report such information and such amount shall be paid to the Treasury.*

*(C) FALSE INFORMATION.—Any manufacturer required to submit information under subsection (f)(2) that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.*

**[(B)] (D) PROCEDURES.**—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under **[(subparagraph (B)] subparagraph (A), (B), or (C)** in the same manner as they apply to a penalty or proceeding under section 1128A(a).

**(5) WIDELY AVAILABLE MARKET PRICE.—**

**(A) IN GENERAL.**—In this subsection, the term “widely available market price” means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

**(B) CONSIDERATIONS.**—In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

- (i) Manufacturers.
- (ii) Wholesalers.
- (iii) Distributors.
- (iv) Physician supply houses.
- (v) Specialty pharmacies.
- (vi) Group purchasing arrangements.
- (vii) Surveys of physicians.
- (viii) Surveys of suppliers.
- (ix) Information on such market prices from insurers.
- (x) Information on such market prices from private health plans.

**(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.**—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) in-

stead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

(f) **QUARTERLY REPORT ON AVERAGE SALES PRICE.**—[For requirements]

(1) *IN GENERAL.*—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1927(b)(3).

(2) *MANUFACTURERS WITHOUT A REBATE AGREEMENT UNDER TITLE XIX.*—

(A) *IN GENERAL.*—In the case of a manufacturer of a drug or biological described in subparagraph (C), (E), or (G) of section 1842(o)(1) or in clause (ii) or (iii) of section 1881(b)(14)(B) that does not have a rebate agreement in effect under section 1927, for calendar quarters beginning on or after January 1, 2020, such manufacturer shall report to the Secretary the information described in subsection (b)(3)(A)(iii) of such section 1927 with respect to such drug or biological in a time and manner specified by the Secretary.

(B) *AUDIT.*—Information reported under subparagraph (A) is subject to audit by the Inspector General of the Department of Health and Human Services.

(C) *VERIFICATION.*—The Secretary may survey wholesalers and manufacturers that directly distribute drugs described in subparagraph (A), when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of such a drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) *CONFIDENTIALITY.*—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph (other than the wholesale acquisition cost for purposes of carrying out this section) is confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B;

(ii) to permit the Comptroller General to review the information provided; and

(iii) to permit the Director of the Congressional Budget Office to review the information provided.

(g) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

(2) the identification of units (and package size) under subsection (b)(2);

(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).

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## INTERNAL REVENUE CODE OF 1986

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## Subtitle F—Procedure and Administration

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## CHAPTER 61—INFORMATION AND RETURNS

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## Subchapter A—RETURNS AND RECORDS

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## PART III—INFORMATION RETURNS

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## Subpart A—INFORMATION CONCERNING PERSONS SUBJECT TO SPECIAL PROVISIONS

Sec. 6031. Return of partnership income.

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Sec. 6039K. Drug price SPIKE increase reporting.

Sec. 6039L. Product samples of applicable manufacturers.

\* \* \* \* \*

### SEC. 6039K. DRUG PRICE SPIKE INCREASE REPORTING.

*Each manufacturer (within the meaning of section 1128L of the Social Security Act) shall file a return (at such time and in such form and manner as the Secretary may provide) showing for such*

*year with respect to which such section applies all information and supporting documentation and the certification included within a justification reported by the manufacturer under subsection (c)(1) of such section.*

**SEC. 6039L. PRODUCT SAMPLES OF APPLICABLE MANUFACTURERS.**

*Each applicable manufacturer (within the meaning of section 1128G(a)(3) of the Social Security Act) shall file a return (at such time and in such form and manner as the Secretary may provide) showing for such year to which such section applies—*

*(1) the amount described in section 1128G(a)(3)(A)(ii) of such Act with respect to such year, and*

*(2) the portion of such amount for which a deduction was claimed under section 162.*

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